REMARKS

Applicant thanks the Examiner for participating in a cordial personal interview with the undersigned on October 20, 2008. The Examiner's rejections under Section 112 and 102(e) / 103 were discussed. Agreement was reached that the rejections under section 112 would be withdrawn for the reasons set forth below. Regarding the rejections under section 102(e) / 103, the Examiner agreed that filling process of the invention distinguished the Duchon reference for reasons noted below. The Examiner committed to seeking a third opinion regarding the claims upon receiving Applicant's response.

Rejection under 35 U.S.C. § 112

Claims 13, 25-27 and 36 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner asserted that "expelling a portion of contrast media that was acquired from the first contrast container out of the syringe through the fill tube and into the second contrast container" is not found in the specification. In reply, Applicant noted that this can be found at page 13, which explains:

> Once the small volume of contrast is in the syringe, the injector system automatically (or the operator, manually) reverses the direction of the injector ram, in step 908, so that the contrast fluid is expelled from the syringe. In particular, the ram is operated such that at least a portion of the fluid in the syringe travels through the fill tube and re-enters the contrast container. Thus, all air is expelled from the fill tube and syringe.

Applicant submits, and the Examiner has concurred, that this text does describe the recited "expelling" process.

Claims 25-27 and 36 were rejected on the basis that the Examiner could not identify disclosure to the effect that the discharge tip is tilted above the barrel during filling, expelling and resuming of filling. In reply, Applicant noted that the process for tilting the injector during filling and expelling is discussed in the background at the top of page 2, and then at page 7, lines 4-8:

> [Page 2] The injection head is typically mounted on the arm in a pivotal manner, so that the head may be tilted upward (with the syringe tip above the remainder of the syringe) to facilitate filling the syringe with fluid, and downward (with the syringe tip below the remainder of the syringe) for injection. Tilting the head in this manner facilitates removal of air from the syringe during filling, and reduces the likelihood that air will be injected into the subject during the injection process.
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> [Page 7] ...as described above, an operator may tilt power head 22 upward, fill syringe 36 from a source of fluid while visually monitoring the filling process, then connect the injector to tubing leading to the patient, expel air from the tubing and syringe while visually monitoring the level of fluid in the syringe, and then once air has been expelled, tilt the injector downward and proceed to inject fluid into a subject.

Applicant submits, and the Examiner has concurred, that this text does describe the tilting aspects of the claimed process.

Rejection under 35 U.S.C. § 102(e)/103

All claims stand rejected as anticipated under 35 U.S.C. § 102(e) or in alternative obvious under 35 U.S.C. § 102(e), in view of the Duchon patent publication. The Examiner asserts that Duchon discloses filling a syringe such that there is air in

the syringe, and posits that "performing remove the substantially all air is inherently and well-known during the filling method, we do not want any air to be injected in to the body".

Applicant in response submits that the specifics identified in the Examiner's remarks do not establish anticipation or obviousness of the present claims.

By way of review, claim 9 recites a method for performing a filling sequence to fill a syringe, in which contrast media is drawn into the syringe through the fill tube at a first fill rate. Subsequently, substantially all air is expelled from the fill tube. Along with this expulsion of air from the filled tube, at least some of the contrast media from within the syringe is also expelled through the fill tube. Thereafter, the syringe is filled at a second fill rate to fill the syringe with the desired fill volume of contrast media; this second fill rate being faster than the first fill rate.

Claim 12 is directed to a method for changing contrast media containers during a syringe filling sequence. In this method, a syringe is filled at at least one of a first fill rate and a second fill rate through a fill tube coupled between the syringe and a first contrast container. This filling step is paused when the first contrast container is substantially emptied. The first contrast container is then replaced with a second contrast container, and the fill tube is coupled between the syringe and the second contrast container. Next, substantially all air is expelled from the fill tube coupled between the syringe and the second contrast container. During this expulsion of the air, at least some of the contrast media is expelled from the syringe, through the fill

tube, and into the second contrast container. After the expulsion of air and contrast media, filling the syringe may be resumed, but this time from the second contrast container at the second fill rate, which is faster than the first fill rate.

Claim 18 recites a syringe filling method for a contrast media injector system. In this method, medical fluid is drawn into a syringe at a first fill rate and, thereafter, at least some of the medical fluid is expelled from the syringe. After the medical fluid is expelled from the syringe, the syringe is filled at a second fill rate that is faster than the first fill rate.

Claim 32 is also directed to a method of operation for a contrast media injector system. In this method, an initial volume of medical fluid is drawn into a syringe of a contrast media injector system at a first fill rate. Next, at least some of the medical fluid is expelled from the syringe. Thereafter, the syringe is filled with medical fluid at a second fill rate that is faster than the first fill rate. Further, a total volume of medical fluid in the syringe after this filling is greater than the initial volume that was drawn into the syringe.

During the Interview, Applicant's representative explained that the portions of the Duchon reference cited by the Examiner (near paragraph [169]) do not show the claimed invention. The key paragraphs of Duchon read as follows:

> [168] In one preferred embodiment, when the volume of contrast material in syringe 411 is less than the injection volume as determined by the microprocessor, the injector system will prevent subsequent injection operations or automatically refill syringe 411. In auto mode or manual mode, syringe 411 can be refilled maximally or to some lesser volume

entered by the operator at console 401. In automatic mode, subsequent to completion of an injection, computer 100 compares the volume of contrast material remaining in syringe 411 with the injection volume preset in the computer by the operator. If the preset injection volume is greater than the volume of contrast material available in syringe 411, computer 100 prevents subsequent patient injection operations. Provided contrast reservoir 413 (or 22) is in place, computer 100 can energize the motor drive circuitry to automatically retract plunger 412 at a set rate, preferably corresponding to a flow rate of about 3 ml per second, to load syringe 411 with contrast material to maximum or other preset volume. Once syringe 411 is filled as indicated by the reverse limit feedback signal from sensor 164, motor 104 moves plunger 412 forward to purge air from the syringe out one-way valve 414 at a rate of about 3 ml per second.

[169] It has also been discovered that by using multiple speeds for retracting of plunger 412 during syringe refill, an air forming bubble within syringe 411 can be reduced more readily. For example, assume a situation where syringe 411 is to be maximally filled. According to this example, the computer controlled retraction of plunger 412 occurs slowly at a rate of about 2 ml per second until filled with about 40 ml of media This slower rate facilitates a forming air bubble to break free from the surface of plunger 412 at the meniscus. Subsequently, a faster rate of about 3 ml per second is used to complete the filling procedure and the bubble released from plunger 412 will tend to float away from the plunger toward one-way valve 414. In addition, angulation of syringe 411 at about 10-20°, preferably about 15° from horizontal facilitates release or movement of an air bubble to one-way valve 14.

As Applicant noted in the interview, what this text is stating is that one can fill a syringe slowly, until an air bubble in the syringe detaches from the plunger, and thereafter, fill faster. This text is clearly <u>not</u> saying that one should fill partially, then expel, then resume filling. That sequence is nowhere suggested in the text quoted above. That specific process, expelling in the midst of a filling process, is recited variously in each independent claim herein.

During the interview, the Examiner noted that the clarity of the claims would be improved by language that establishes that the claimed method relates to a single filling process. The Examiner suggested that the sequence of the method be clarified, and the placement of the fill tube on the syringe be recited in various claims to establish the beginning point of the method. This request has been handled in the attached amendment.

In view of this amendment, and the reasons articulated by Applicant, this application is submitted to be in complete condition for allowance and early notice to this effect is earnestly solicited. If there is any issue that remains which may be resolved by telephone conference, Examiner is invited to contact the undersigned in order to resolve the same and expedite the allowance of this application.

Applicants do not believe that this response requires that any claim fees be submitted, however, if any fees are deemed necessary, these may be charged to Deposit Account No. 23-3000.

Respectfully submitted,

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